DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 13, 2014

RADIOMETER MEDICAL APS
SOREN BOGESTRAND
REGULATORY AFFAIRS SPECIALIST
AKANDEVEJ 21
BRONSHOJ DK-2700

Re: K132691
Trade/Device Name: ABL90 Flex
Regulation Number: 21 CFR 862.1113
Regulation Name: Bilirubin (total and unbound) in the neonate test system
Regulatory Class: I, reserved
Product Code: MQM
Dated: October 24, 2014
Received: October 31, 2014

Dear Mr. Bogestrand:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K132691

Device Name
ABL90 FLEX

Indications for Use *(Describe)*

Intended Use:
The ABL90 FLEX analyzer is an in vitro diagnostic, portable, automated analyzer that quantitatively measures neonatal bilirubin in heparinised capillary whole blood. The ABL90 FLEX analyzer is intended for use by trained technologists, nurses, physicians and therapists. It is intended for use in a laboratory environment, near patient or point-of-care setting. These tests are only performed under a physician's order. Bilirubin measurements on the ABL90 FLEX analyzer are intended to aid in assessing the risk of kernicterus in neonates.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

1. Submitter and contact information

Submitter

Company Name: Radiometer Medical ApS
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Date prepared

Date: November 11, 2014

2. a. Device Information

Device Name: ABL90 FLEX analyzer
Common Name: Blood gases, Cooximetry, and Metabolite analyzer

Classification:

Classification name	CFR Section	Device Class	Product Code
Bilirubin in the neonate test system	862.1113	I,reserved	MQM

2. b. Device Description

Instrument name, manufacturer, models and accessories

The name of the device is the ABL90 FLEX. The device is manufactured by Radiometer Medical ApS, Brønshøj, Denmark.

The ABL90 FLEX is a portable, automated system intended for in vitro testing of samples of whole blood for the parameters pH, pO2, pCO2, potassium, sodium, calcium, chloride, glucose, lactate, neonatal bilirubin and co-oximetry parameters (total hemoglobin, oxygen saturation, and the hemoglobin fractions *F*O_2Hb, *F*COHb, *F*MetHb, *F*HHb and *F*HbF).

The ABL90 FLEX consists of an instrument with a sensor cassette and a solution pack as the main accessories. Multiple models of sensor cassettes are available.

The various sensor cassette models include models for different parameter combinations. For each parameter combination, models allowing for different test load are available.

The solution pack is available in one model.

The ABL 90 FLEX electrochemical sensors are miniaturized, manufactured by film technology and integrated in a common sensor cassette. Likewise, the ABL90 FLEX optical oxygen sensor is integrated in the sensor cassette. A 256-pixel array spectrophotometer is used for the co-oximetry parameters and bilirubin.

2. c. Purpose of submission

Addition of neonatal bilirubin measurement to previously cleared ABL90 FLEX analyzer (K092686)

Clinical Utility neonatal Bilirubin

Neonatal Bilirubin test is intended for use to aid in assessing the risk of kernicterus in neonates.

3. Intended Use / Indications for use

The ABL90 FLEX analyzer is an in vitro diagnostic, portable, automated analyzer that quantitatively measures neonatal bilirubin in heparinised capillary whole blood. The ABL90 FLEX analyzer is intended for use by trained technologists, nurses, physicians and therapists. It is intended for use in a laboratory environment, near patient or point-of-care setting. These tests are only performed under a physician's order. Bilirubin measurements on the ABL90 FLEX analyzer are intended to aid in assessing the risk of kernicterus in neonates.

4. Predicate device: ABL800 FLEX analyzer (K050869)

Substantial Equivalence

The ABL90 FLEX analyzer with neonatal bilirubin is substantially equivalent in Intended Use, fundamental scientific technology, features, and characteristics to the predicate:

510(k) Number/Device Manufacturer:

K050869 ABL800 FLEX, Radiometer Medical ApS

Similarities		
Issue	**SE Device**	**Predicate Device (K050869)**
Intended use	The ABL90 FLEX analyzer is an in vitro diagnostic, portable, automated analyzer that quantitatively measures neonatal bilirubin in heparinised capillary whole blood. The ABL90 FLEX analyzer is intended for use by trained technologists, nurses, physicians and therapists. It is intended for use in a laboratory environment, near patient or point-of-care setting. These tests are only performed under a physician's order. Bilirubin measurements on the ABL90 FLEX analyzer are intended to aid in assessing the risk of kernicterus in neonates.	Same
Measuring method for neonate bilirubin test	Using spectrophotometric multi-component analysis through the instrument's existing CO-Oximetry module on a hemolyzed part of the sample.	Same
Calibration Method for neonate bilirubin test	Two-point liquid calibration.	Same

Differences		
Issue	**SE Device**	**Predicate Device (K050869)**
Intended use site	Clinical laboratory and point-of-care.	Clinical laboratory.
Neonatal bilirubin reportable range	μmol/L: 28 – 648 mg/dL: 1.6 – 37.9 mg/L: 16 – 379	μmol/L: 1 - 1000 mg/dL: 0.0 – 58.5 mg/L: 0 - 585

5. Performance Characteristics

Precision

Repeatability and Device/Method Precision was evaluated according to CLSI guideline "Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second Edition", EP05-A2. The study was conducted at three point-of-care (POC) sites and on two instruments in Radiometer's laboratory facility on aqueous samples. In addition, a one-day study was conducted using spiked adult whole blood samples adjusted to mimic neonatal whole blood.

The test verified that neonatal bilirubin can be measured with acceptable precision in both POC and laboratory settings and in both capillary and syringe mode.

Point-of-care studies

20 day precision performance on aqueous solutions, all sites pooled:

Capillary mode:

Sample	N	Mean (mg/dL)	Within run, Sr		Total, ST	
			SD (Sr)	%CV	SD (ST)	%CV
Sample 1	240	2.1	0.04	2.1	0.08	3.8
Sample 2	240	7.4	0.09	1.2	0.11	1.5
Sample 3	240	30.6	0.32	1.1	0.42	1.4

Syringe mode:

Sample	N	Mean (mg/dL)	Within run, Sr		Total, ST	
			SD (Sr)	%CV	SD (ST)	%CV
Sample 1	240	2.1	0.06	2.7	0.10	4.6
Sample 2	240	7.4	0.06	0.8	0.11	1.5
Sample 3	240	30.7	0.20	0.7	0.40	1.3

20 day precision performance on aqueous solutions, site 1:

Capillary mode:

Sample	N	Mean (mg/dL)	Within run, Sr		Total, ST	
			SD (Sr)	%CV	SD (ST)	%CV
Sample 1	80	2.1	0.04	1.8	0.08	3.7
Sample 2	80	7.3	0.06	0.8	0.10	1.3
Sample 3	80	30.2	0.19	0.6	0.49	1.6

Syringe mode:

Sample	N	Mean (mg/dL)	Within run, Sr		Total, ST	
			SD (Sr)	%CV	SD (ST)	%CV
Sample 1	80	2.1	0.05	2.4	0.08	4.1
Sample 2	80	7.3	0.05	0.7	0.09	1.3
Sample 3	80	30.3	0.09	0.3	0.50	1.6

20 day precision performance on aqueous solutions, site 2:

Capillary mode:

Sample	N	Mean (mg/dL)	Within run, Sr		Total, ST	
			SD (Sr)	%CV	SD (ST)	%CV
Sample 1	80	2.2	0.05	2.3	0.08	3.6
Sample 2	80	7.5	0.10	1.4	0.13	1.7
Sample 3	80	31.3	0.38	1.2	0.40	1.3

Syringe mode:

Sample	N	Mean (mg/dL)	Within run, Sr		Total, ST	
			SD (Sr)	%CV	SD (ST)	%CV
Sample 1	80	2.2	0.06	2.9	0.11	4.9
Sample 2	80	7.6	0.07	0.9	0.13	1.6
Sample 3	80	31.6	0.28	0.9	0.41	1.3

20 day precision performance on aqueous solutions, site 3:

Capillary mode:

Sample	N	Mean (mg/dL)	Within run, Sr		Total, ST	
			SD (Sr)	%CV	SD (ST)	%CV
Sample 1	80	2.1	0.05	2.3	0.09	4.2
Sample 2	80	7.3	0.09	1.2	0.11	1.5
Sample 3	80	30.3	0.37	1.2	0.34	1.1

Syringe mode:

Sample	N	Mean (mg/dL)	Within run, Sr		Total, ST	
			SD (Sr)	%CV	SD (ST)	%CV
Sample 1	80	2.1	0.06	2.8	0.10	4.8
Sample 2	80	7.3	0.06	0.9	0.11	1.5
Sample 3	80	30.4	0.20	0.7	0.27	0.9

1 day precision performance on spiked adult whole blood, all sites pooled:

Capillary mode:

Sample	N	Mean (mg/dL)	Within run, Sr		Total, ST	
			SD (Sr)	%CV	SD (ST)	%CV
Sample 1	75	2.1	0.12	5.7	0.30	14.0
Sample 2	75	7.1	0.16	2.3	0.44	6.3
Sample 3	75	30.0	0.28	0.9	0.49	1.6

Syringe mode:

Sample	N	Mean (mg/dL)	Within run, Sr		Total, ST	
			SD (Sr)	%CV	SD (ST)	%CV
Sample 1	75	2.5	0.13	5.0	0.22	8.7
Sample 2	75	7.2	0.14	2.0	0.21	2.9
Sample 3	75	30.8	0.27	0.9	0.31	1.0

1 day precision performance on spiked adult whole blood, site 1:

Capillary mode:

Sample	N	Mean (mg/dL)	Within run, Sr		Total, ST	
			SD (Sr)	%CV	SD (ST)	%CV
Sample 1	25	2.3	0.14	6.1	0.31	13.4
Sample 2	25	7.1	0.15	2.1	0.61	8.5
Sample 3	25	30.4	0.16	0.5	0.37	1.2

Syringe mode:

Sample	N	Mean (mg/dL)	Within run, Sr		Total, ST	
			SD (Sr)	%CV	SD (ST)	%CV
Sample 1	25	2.5	0.12	4.8	0.12	4.9
Sample 2	25	7.2	0.14	1.9	0.14	1.9
Sample 3	25	31.1	0.21	0.7	0.19	0.6

1 day precision performance on spiked adult whole blood, site 2:

Capillary mode:

Sample	N	Mean (mg/dL)	Within run, Sr		Total, ST	
			SD (Sr)	%CV	SD (ST)	%CV
Sample 1	25	1.8	0.11	5.7	0.14	7.3
Sample 2	25	7.2	0.19	2.6	0.20	2.8
Sample 3	25	29.5	0.22	0.7	0.41	1.4

Syringe mode:

Sample	N	Mean (mg/dL)	Within run, Sr		Total, ST	
			SD (Sr)	%CV	SD (ST)	%CV
Sample 1	25	2.6	0.11	4.2	0.12	4.5
Sample 2	25	7.5	0.16	2.1	0.15	2.0
Sample 3	25	30.9	0.21	0.7	0.20	0.6

1 day precision performance on spiked adult whole blood, site 3:

Capillary mode:

Sample	N	Mean (mg/dL)	Within run, Sr		Total, ST	
			SD (Sr)	%CV	SD (ST)	%CV
Sample 1	25	2.2	0.11	5.2	0.39	17.7
Sample 2	25	6.9	0.14	2.1	0.42	6.2
Sample 3	25	30.0	0.40	1.3	0.65	2.2

Syringe mode:

Sample	N	Mean (mg/dL)	Within run, Sr		Total, ST	
			SD (Sr)	%CV	SD (ST)	%CV
Sample 1	25	2.4	0.15	6.1	0.34	13.9
Sample 2	25	6.8	0.13	1.9	0.30	4.5
Sample 3	25	30.5	0.36	1.2	0.46	1.5

Laboratory studies

Precision study on aqueous solutions, 20 days:

Capillary mode:

Sample	N	Mean (mg/dL)	Within run, Sr		Total, ST	
			SD (Sr)	%CV	SD (ST)	%CV
Sample 1	80	2.1	0.05	2.3	0.07	3.4
Sample 2	80	7.4	0.12	1.6	0.13	1.7
Sample 3	80	30.7	0.48	1.6	0.46	1.5

Syringe mode:

Sample	N	Mean (mg/dL)	Within run, Sr		Total, ST	
			SD (Sr)	%CV	SD (ST)	%CV
Sample 1	80	2.1	0.05	2.4	0.07	3.2
Sample 2	80	7.4	0.11	1.5	0.14	1.9
Sample 3	80	30.9	0.45	1.4	0.57	1.8

1 day precision performance on spiked adult whole blood and cord blood:

Capillary mode:

Sample	N	Mean (mg/dL)	Within run, Sr		Total, ST	
			SD (Sr)	%CV	SD (ST)	%CV
Sample 1, Adult blood	25	2.3	0.15	6.7	0.18	7.7
Sample 2, Adult blood	25	7.8	0.22	2.8	0.34	4.4
Sample 3, Adult blood	25	30.2	0.73	2.4	0.80	2.6
Sample 1, Cord blood	25	2.0	0.10	4.9	0.13	6.7
Sample 2, Cord blood	25	7.0	0.19	2.7	0.24	3.4
Sample 3, Cord blood	25	30.6	0.32	1.1	0.34	1.1

Syringe mode:

Sample	N	Mean (mg/dL)	Within run, Sr		Total, ST	
			SD (Sr)	%CV	SD (ST)	%CV
Sample 1, Adult blood	25	2.6	0.13	5.0	0.21	8.3
Sample 2, Adult blood	25	7.4	0.09	1.2	0.15	2.1
Sample 3, Adult blood	25	29.4	0.51	1.7	0.52	1.8
Sample 1, Cord blood	25	2.4	0.12	4.9	0.18	7.4
Sample 2, Cord blood	25	7.1	0.24	3.4	0.28	4.0
Sample 3, Cord blood	25	29.9	0.21	0.7	0.26	0.9

Method Comparison
Method comparison study versus the predicate has been conducted according to NCCLS guideline "Method Comparison and Bias Estimation Using Patient Samples", EP09-A2. The study was conducted for both capillary and syringe mode at three point-of-care sites and included a total of 224 samples for capillary mode and 210 samples for syringe mode spanning the entire measuring range.

Linear regression of the pooled data gives a slope of 0.9903/0.9760 and an R^2 of 0.99/0.99 for syringe and capillary mode respectively showing good correlation with the predicate device and very good agreement between the two modes.

Syringe mode:

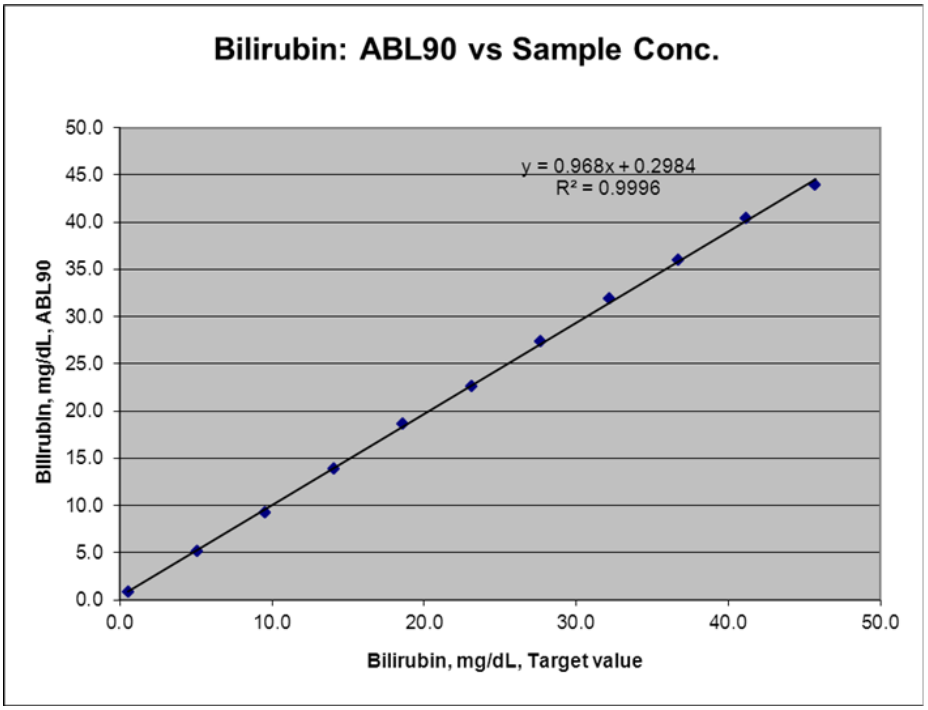
Site	N	ABL 90 FLEX range tested, mg/dL	Slope (95% CI)	Intercept (95% CI) mg/dL	R^2
Site 1	74	1.8 – 35.9	0.9922 (0.964 – 1.020)	1.0207 (0.64 – 1.40)	0.9857
Site 2	51	2.0 – 37.9	1.0054 (0.980 – 1.031)	0.3744 (0.00 – 0.75)	0.9924
Site 3	85	2.7 – 37.1	0.9917 (0.969 – 1.014)	0.3623 (0.01 – 0.71)	0.9895
All sites combined	210	1.8 – 37.9	0.9903 (0.975 – 1.005)	0.6574 (0.44 – 0.88)	0.9878

Capillary mode:

Site	N	ABL 90 FLEX range tested, mg/dL	Slope (95% CI)	Intercept (95% CI) mg/dL	R^2
Site 1	77	1.8 – 35.5	0.9774 (0.950 – 1.005)	1.1199 (0.76 – 1.48)	0.9853
Site 2	56	2.1 – 37.3	0.9977 (0.974 – 1.021)	0.5385 (0.19 – 0.88)	0.9927
Site 3	91	3.0 – 36.7	0.9737 (0.948 – 0.999)	0.4862 (0.09 – 0.88)	0.9845
All sites combined	224	1.8 – 37.3	0.9760 (0.961 – 0.991)	0.7741 (0.55 – 1.00)	0.9861

Linearity
Linearity study has been conducted according to CLSI guideline "Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline", EP6-A.

The method is linear (first order) over the entire measuring range and fulfils the requirements for allowable error due to non-linearity established by Radiometer.



Interference
Interference study has been conducted according to CLSI guideline "Interference Testing in Clinical Chemistry; Approved Guideline – Second Edition", EP07-A2.

Significant interference was observed from Fluorescein, Beta-carotene, Methylene Blue, Patent Blue V, Cardio Green, HiCN, Hydroxycobalamin, Cyanocobalamin, and SHb.

No clinically significant interference was observed from Evans Blue, HbF, Hemolysis, Intralipid or Triglyceride. Interference specifications are tabulated below.

There was non-significant interference with Evans Blue, Intralipid, HbF, Hemolysis, and Triglyceride at the highest concentration indicated below: (Sponsor defines non-significant interference as < ± 10%)

Substances tested	Highest concentration tested with non-significant interference
Evans Blue	5 mg/L
Intralipid	1000 mg/dL
HbF	82%
Hemolysis	20% (equivalent to approximately 3 g/dL hemoglobin)
Triglyceride	500 mg/dL

There was significant interference for Fluorescein, Patent Blue V, Methylene Blue, Cardio Green, SHb, Hydroxocobalamin Hydrochloride, and Cyanocobalamin (Sponsor defines significant interference as ≥ ± 10%). Dose-response studies were conducted to determine the highest levels of interferents at which significant interference could not be seen, the results are tabulated below:

Interferents tested	Bilirubin concentration tested (mg/dL)	Highest level of interferent free from significant interference
Fluorescein	5	1.5 mg/L
	15	4 mg/L
Patent Blue V	5	1.5 mg/L
	15	2.5 mg/L
Methylene Blue	5	0.75 mg/L
	15	2 mg/L
Cardio Green	5	3 mg/L
	15	10 mg/L
SHb	5	1.1%
	15	1.6%

Hydroxocobalamin Hydrochloride	5	0.19 g/L
	15	0.5 g/L
Cyanocobalamin	5	0.2 g/L
	15	0.7 g/L

pH was tested in the range from 6.8 – 7.9 and significant interference relative to physiological pH was not observed.

Limitation in the labeling: Since the spectra for HiCN and Beta-carotene overlap with the spectrum of bilirubin, these are known interfering substances. Results from samples containing these substances should not be used.

LoB, LoD, LoQ
Study has been conducted according to CLSI guideline "Protocols for Determination of Limits of Detection and Limits of Quantitation; Approved Guideline", EP17-A2.

LoB was determined to be 1.1 mg/dL (18 µmol/L).
LoD was determined to be 1.60 mg/dL (27.4 µmol/L)
LoQ was determined to be 1.60 mg/dL (27.4 µmol/L)

6. Conclusion
Based on the substantial equivalence comparison and the results of the conducted performance evaluations it has been concluded that the ABL90 FLEX analyzer with neonatal bilirubin is as safe and effective as the predicate device.